

Aroseptic Pulvis Antisepticus failed to bear the common or usual name of each active ingredient; 502 (f) (1)—the labeling of the *Aroseptic* failed to bear adequate directions for use as a douche, and the labeling of *Petty's toothache drops* bore no directions for use; 502 (f) (2)—the labeling of *Petty's pile ointment*, *Petty's Heal-Aid ointment*, and *Petty's Aroseptic Pulvis Antisepticus* failed to bear adequate warnings against use in bleeding piles, and the labeling of *Petty's toothache drops* failed to warn that the article was only for temporary use until a dentist could be consulted.

DISPOSITION: 8-2-55. Default—destruction.

DRUG AND DEVICE ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

4991. Dried stillingia root. (F. D. C. No. 39120. S. No. 2-128 M.)

QUANTITY: 14 50-lb bags at Marion, Va., in possession of R. T. Greer & Co.

SHIPPED: Between 4-12-55 and 7-12-55, from Fort Myers, Fla.

LBELED: 4-30-56, W. Dist. Va.

CHARGE: 501 (a) (1)—contained rodent hairs and rodent urine; and 501 (a) (2)—held under insanitary conditions.

DISPOSITION: 6-14-56. Default—destruction.

4992. Rubber prophylactics. (F. D. C. No. 38713. S. No. 40-504 M.)

QUANTITY: 1,008 rubber prophylactics at St. Paul, Minn.

SHIPPED: 8-4-55 and 9-7-55, from North Kansas City, Mo., by Dean Rubber Mfg. Co.

LABEL IN PART: (Carton containing 3 prophylactics) "Peacocks Redi-Wet Rubbers In Foil * * * Hygienically Lubricated * * * These Redi-Wet Peacock Rubbers are hygienically Pre-Lubricated with proven exclusive formula."

RESULTS OF INVESTIGATION: Examination showed that the article consisted of rolled rubber prophylactics packaged individually in hermetically sealed metal foil containers. Each rubber prophylactic was moistened with a small amount of viscous liquid, intended to act as a lubricant during coitus. This liquid coating on the individual prophylactics was contaminated with an extensive and obvious mold growth.

LBELED: 11-23-55, Dist. Minn.

CHARGE: 501 (a) (1)—contained, when shipped, a decomposed substance by reason of contamination with mold; 501 (c)—the purity and quality of the article fell below that which it purported and was represented to possess since the lubricant liquid used to coat the individual rubber prophylactics was contaminated with an extensive mold growth; and 502 (a)—the label statement "Hygienically Lubricated" was false and misleading as applied to a product contaminated with extensive mold growth.

DISPOSITION: 1-5-56. Default—destruction.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

4993. Elixir of terpin hydrate and codeine (2 seizure actions). (F. D. C. No. 38651. S. Nos. 23-837 M, 23-851 M.)

QUANTITY: 240 2-oz. btls. at Phoenix, Ariz.

*See also Nos. 4986, 4992.

SHIPPED: 2-2-55 and 9-1-55, from Los Angeles, Calif., by Rabin Co.

LABEL IN PART: (Btl.) "Gray Cross * * * Elixir of Terpin Hydrate and Codeine, N. F."

RESULTS OF INVESTIGATION: Analysis showed that the article contained 67 percent of the declared amount of codeine.

LIBELED: 10-28-55 and 11-8-55, Dist. Ariz.

CHARGE: 501 (b)—the article, when shipped, purported to be and was represented as a drug, "Elixir of Terpin Hydrate and Codeine," the name of which is recognized in the National Formulary, an official compendium, and its strength differed from the standard set forth in such compendium; and 502 (a)—the label statement "Each fluid ounce contains Codeine * * * 0.9 gr." was false and misleading.

DISPOSITION: 12-22-55. Default—destruction.

4994. Amphetoplex tablets. (F. D. C. No. 38645. S. No. 32-023 M.)

QUANTITY: 1 drum containing 50,000 tablets at Philadelphia, Pa., in possession of Continental Medical Supply Co.

SHIPPED: 7-7-55, from Camden, N. J.

RESULTS OF INVESTIGATION: Analysis showed that the article contained less than 70 percent of the declared amount of vitamin B₁ (thiamine HCl).

LIBELED: 10-18-55, E. Dist. Pa.

CHARGE: 501 (c)—the strength of the article, while held for sale, differed from that which it purported and was represented to possess, namely, 1.5 milligrams of vitamin B₁ per tablet; and 502 (a)—the statement appearing in the labeling of the article "Each tablet contains: Thiamine HCl . . . 1.5 mgm." was false and misleading.

DISPOSITION: 12-14-55. Default—destruction.

4995. Vitamin B complex with vitamin B₁₂. (F. D. C. No. 38667. S. No. 32-124 M.)

QUANTITY: 101 10-cc. vials at Camden, N. J.

SHIPPED: On 9-27-54, the article was shipped from Newark, N. J., to the consignee, who was doing business in Philadelphia, Pa. The consignee subsequently moved and transported the article to its place of business in Camden, N. J.

RESULTS OF INVESTIGATION: Analysis showed that the article contained less than 25 percent of the declared amount of vitamin B₁₂.

LIBELED: On or about 11-7-55, Dist. N. J.

CHARGE: 501 (c)—the strength of the article, while held for sale, differed from that which it purported and was represented to possess, namely, 15 micrograms of vitamin B₁₂ per cubic centimeter; and 502 (a)—the label statement "Each cc. Contains * * * Vitamin B-12 . . . 15 mcg." was false and misleading.

DISPOSITION: 12-6-55. Default—the words "with Vitamin B-12" and "Vitamin B-12 . . . 15 mcg." were stricken from the labeling, and the article was delivered to a charitable institution.

4996. Liver-iron folic acid. (F. D. C. No. 38680. S. No. 32-122 M.)

QUANTITY: 53 25-cc. vials at Camden, N. J.

SHIPPED: 6-1-55, from Philadelphia, Pa.